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**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS**

JESSE MITCHELL and KIMBERLY
MITCHELL, husband and wife,

MDL No. 2545

Plaintiffs,

**COMPLAINT AND DEMAND FOR
JURY TRIAL**

vs.

ABBVIE, INC. and ABBOTT
LABORATORIES, INC.,

Defendants.

COMPLAINT

Plaintiffs, Jesse Mitchell and Kimberly Mitchell (hereinafter "Plaintiffs"), residing in Fairview, Multnomah County within the State of Oregon, by and through their undersigned counsel, hereby sue Defendants AbbVie Inc. and Abbott Laboratories, Inc. ("Defendants") and allege as follows:

INTRODUCTION

1
2 1. This case involves the prescription drug AndroGel, which is manufactured, sold,
3 distributed and promoted by Defendants as a testosterone replacement therapy.

4 2. Defendants misrepresented that AndroGel was a safe and effective treatment for
5 hypogonadism when in fact the drug causes serious medical problems, including life threatening
6 cardiac events, strokes, and thrombolytic events.

7 3. Defendants engaged in aggressive, award-winning direct-to-consumer and
8 physician marketing, and advertising campaigns for AndroGel. Further, Defendants engaged in
9 an aggressive, unbranded “disease awareness” campaign to alert men that they might be
10 suffering from a disease defendants created called “low T”, which is Defendants’ abbreviated
11 phrase for “low testosterone.”

12 4. According to the industry-leading “Androgen Deficiency in Adult Males
13 (“ADAM”) or “Is it Low T?” quiz, the symptoms of “Low T” include “feeling “sad or grumpy,”
14 “experiencing deterioration in the ability to play sports,” and “falling asleep after dinner.”
15 Available at: <http://www.isitlowt.com/do-you-have-low-t/low-t-quiz>. Most doctors agree that
16 these symptoms can be caused by an abundance of factors, the most prominent of which is the
17 natural aging process.

18 5. As a result of this “disease mongering,” as termed by Dr. Adriene Fugh-Berman of
19 Georgetown University Medical Center, diagnoses of “Low T” have increased exponentially.
20 This has directly related to AndroGel’s sales increasing to over \$1.37 billion per year.

21 6. However, consumers of AndroGel were misled as to the drug’s safety and
22 efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes,
23 and thrombolytic events.

PARTIES

24 7. Plaintiffs are citizens of Fairview, Oregon.
25

9. Defendant, Abbot Laboratories, Inc. is a corporation organized and existing under the laws of the state of Illinois and maintains its principal place of business at 100 Abbot Park Road, Abbott Park, Illinois 60064.

JURISDICTION AND VENUE

12. Venue of this case is appropriate in the United States District Court for the Northern District of Illinois, pursuant to Judge Matthew F. Kennelly's Order, which permits directly filing into the United States District Court for the Northern District of Illinois, under Case MDL No. 2545, *In re: Testosterone Replacement Therapy Products Liability Litigation*.

13. This action is for damages brought on behalf of Plaintiff, Jesse Mitchell, who was prescribed and supplied with, received and who has taken and applied the prescription drug AndroGel, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed,

1 labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the
2 stream of interstate commerce by Defendants. This action seeks, among other relief, general and
3 special damages and equitable relief in order to enable the Plaintiff, Jesse Mitchell, to treat and
4 monitor the dangerous, severe, and life-threatening side effects caused by this drug.

5 14. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused
6 Plaintiff's injuries and damages.

7 15. At all times herein mentioned, the Defendants were engaged in the business of,
8 or were successors in interest to, entities engaged in the business of research, licensing,
9 designing, formulating, compounding, testing, manufacturing, producing, processing,
10 assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or
11 advertising for sale or selling the prescription drug AndroGel for the use and application by
12 the consuming public.

13 16. At all times herein mentioned, Defendants were authorized to do business within
14 Plaintiffs' state of residence.

15 17. At all times herein mentioned, the officers and directors of Defendants participated
16 in, authorized, and directed the production and promotion of the aforementioned product when
17 they knew, or with the exercise of reasonable care should have known, of the hazards and
18 dangerous propensities of said product and thereby actively participated in the tortious conduct
19 which resulted in the injuries suffered by Plaintiff Jesse Mitchell herein.

20 18. Plaintiffs file this lawsuit within the applicable limitations period of first
21 suspecting that said drugs caused the appreciable harm sustained by Plaintiff Jesse Mitchell.
22 Plaintiffs could not, by the exercise of reasonable diligence, have discovered Plaintiff's injuries
23 or losses at an earlier time because the injuries or losses were caused without perceptible trauma
24 or harm, and when the Plaintiff's injuries or losses were discovered their cause was unknown to
25 Plaintiffs. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, that Plaintiff Jesse
Mitchell had been injured, the cause of the injuries, or the tortious nature of the conduct causing

1 the injuries, until less than the applicable limitations period prior to the filing of this action.
2 Additionally, Plaintiffs were prevented from discovering this information sooner because
3 Defendants herein misrepresented and continue to misrepresent to the public and to the medical
4 profession that the drug AndroGel is safe and free from serious side effects, and Defendants
5 have fraudulently concealed facts and information that could have led Plaintiffs to discover a
6 potential cause of action.

7 OVERVIEW

8 19. Hypogonadism is a specific condition of the sex glands, which in men may
9 involve the diminished production or nonproduction of testosterone.

10 20. In 1999, when Unimed Pharmaceuticals Inc., one of the Defendants' predecessor
11 companies, asked for FDA approval of AndroGel, it asserted that hypogonadism was estimated
12 to affect approximately "one million American men."

13 21. In 2000, when the FDA approved AndroGel, the company announced that the
14 market was "four to five million American men." By 2003, the number increased to "up to 20
15 million men." However, a study published in the Journal of the American Medical Association
16 ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001-
17 2011" indicated that many men who get testosterone prescriptions have no evidence of
18 hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue,
19 and one quarter of men did not even have their testosterone levels tested before they received a
20 testosterone prescription.

21 22. Defendants coordinated a massive advertising campaign designed to convince men
22 that they suffered from low testosterone. Defendants orchestrated a national disease awareness
23 media blitz that purported to educate male consumers about the signs of low testosterone. The
24 marketing campaign consisted of television advertisements, promotional literature placed in
25 healthcare providers' offices and distributed to potential AndroGel users, and online media
including the unbranded website ["IsItLowT.com."](http://IsItLowT.com)

1 23. The television advertisements suggest that various symptoms often associated with
2 other conditions may be caused by low testosterone and encourage men to discuss testosterone
3 replacement therapy with their doctors if they experienced any of the "symptoms" of low
4 testosterone. These "symptoms" include listlessness, increased body fat, and moodiness—all
5 general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low
6 testosterone.

7 24. Defendants' national education campaign included the creation and continued
8 operation of the website www.IsItLowT.com. The website asserts that millions of otherwise
9 healthy men experience low testosterone and encourages male visitors to "Take the 'Is it Low T'
10 Quiz." The "Is it Low T" quiz asks men if they have experienced potential signs of low
11 testosterone, including "Have you experienced a recent deterioration in your ability to play
12 sports?", "Are you falling asleep after dinner?", "Are you sad and/or grumpy?", and "Do you
13 have a lack of energy?"

14 25. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis
15 University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical
16 company Organon BioSciences, in exchange for a \$40,000 grant to his university. The
17 pharmaceutical company instructed Dr. Morley, "Don't make it too long and make it somewhat
18 sexy." Dr. Morely drafted the questionnaire in 20 minutes in the bathroom, scribbling the
19 questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morely
20 admits that he has "no trouble calling it a crappy questionnaire" and that it is "not ideal." This is
21 the "Low T Quiz" used on the "IsItLowT" website. Natasha Singer, *Selling that New-Man*
22 *Feeling*, Nov. 23, 2013, N.Y. TIMES.

23 26. Since the FDA approved AndroGel, Defendants have also sought to convince
24 primary care physicians that low testosterone levels are widely under-diagnosed, and that
25 conditions associated with normal aging could be caused by low testosterone levels.

1 27. While running their disease awareness campaign, Defendants promoted their
2 product AndroGel as an easy to use topical testosterone replacement therapy. Defendants
3 contrast their product's at-home topical application with less convenient prescription
4 testosterone injections, which require frequent doctor visits.

5 28. Defendants convinced millions of men to discuss testosterone replacement therapy
6 with their doctors, and consumers and their physicians relied on Defendants' promises of safety
7 and ease. Although prescription testosterone replacement therapy had been available for years,
8 millions of men who had never been prescribed testosterone flocked to their doctors and
9 pharmacies.

10 29. What consumers received, however, were not safe drugs, but a product which
11 causes life-threatening problems, including strokes and heart attacks.

12 30. Defendants successfully created a robust and previously nonexistent market for
13 their drug. Defendant Abbott Laboratories spent \$80 million promoting AndroGel in 2012. The
14 company also spent millions on its unbranded marketing including commercials and its
15 websites, www.IsItLowT.com and www.DriveForFive.com, sites which recommend that men
16 have regular checkups with their physicians and five regular tests done: including cholesterol,
17 blood pressure, blood sugar, prostate-specific antigen, and testosterone.

18 31. Defendants' advertising paid off in a return of \$1.4 billion in sales during the past
19 year, making AndroGel the biggest selling androgen drug in the United States. Sales of
20 replacement therapies have more than doubled since 2006, and are expected to triple to \$5
21 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are*
22 *Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg Businessweek, available at:
23 <http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra>.

24 32. In early 2013, Medical Marketing & Media named two AbbVie executives as "the
25 all-star large pharma marketing team of the year" for promotions of AndroGel and unbranded
efforts to advance low T. See Singer, *Selling That New-Man Feeling*, *supra*; See also, Larry

1 Dobrow, *All-star large pharma marketing team of the year. Androgel*. Jan. 2, 2013, Medical
2 Marketing & Media, available at: [http://www.mmm-online.com/all-star-large-pharma-](http://www.mmm-online.com/all-star-large-pharma-marketing-team-of-the-year-androgel/article/273242/)
3 [marketing-team-of-the-year-androgel/article/273242/](http://www.mmm-online.com/all-star-large-pharma-marketing-team-of-the-year-androgel/article/273242/).

4 33. The marketing program sought to create the image and belief by consumers and
5 physicians that low testosterone affected a large number of men in the United States and that the
6 use of AndroGel is safe for human use, even though Defendants knew these to be false, and
7 even though Defendants had no reasonable grounds to believe them to be true.

8 34. There have been a number of studies indicating that testosterone in men increases
9 the risk of heart attacks and strokes.

10 35. In 2010, a New England Journal of Medicine Study entitled “Adverse Events
11 Associated with Testosterone Administration” was discontinued after an exceedingly high
12 number of men in the testosterone group suffered adverse events.

13 36. In November of 2013, a JAMA study was released entitled “Association of
14 Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low
15 Testosterone Levels” which indicated that testosterone therapy raised the risk of death, heart
16 attack and stroke by about 30%.

17 37. On January 29, 2014, a study was released in PLOS ONE entitled “Increased Risk
18 of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men”
19 which indicated that testosterone use doubled the risk of heart attacks in men over sixty five
20 years old and men younger than sixty-five with a previous diagnosis of heart disease.

21 **FACTUAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION**

22 38. The Food and Drug Administration approved AndroGel 1% on February 28, 2000
23 for the treatment of adult males who have low or no testosterone and AndroGel 1.62% was
24 approved in April, 2011. After FDA approval, AndroGel was widely advertised and marketed by
25 Defendant as a safe and effective testosterone replacement therapy.

1 39. AndroGel, is a hydroalcoholic gel containing testosterone in either 1% or 1.62%,
2 applied to the chest, arms or stomach and enters the body through transdermal absorption. The
3 AndroGel 1.62% product also contains isopropyl myristate as an ointment and ethanol for
4 absorption enhancement.

5 40. Testosterone is a primary androgenic hormone responsible for normal growth,
6 development of the male sex organs, and maintenance of secondary sex characteristics.

7 41. The hormone plays a role in sperm production, fat distribution, maintenance of
8 muscle strength and mass, and sex drive.

9 42. In men, testosterone levels normally begin a gradual decline after the age of
10 thirty.

11 43. The average testosterone levels for most men range from 300 to 1,000 nanograms
12 per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many
13 factors, including sleep, time of day, and medication. Resultantly, many men who fall into the
14 hypogonadal range one day will have normal testosterone levels the next.

15 44. AndroGel produces undesirable side effects to patients who use the drug,
16 including but not limited to, myocardial infarction, stroke, and death.

17 45. In some patient populations, AndroGel use may increase the incidence of
18 myocardial infarctions and death by over 500%.

19 46. In addition to the above, AndroGel has been linked to several severe and life
20 changing medical disorders in both users and those who come into physical contact with users or
21 the unwashed clothes of someone who applied AndroGel. Patients taking AndroGel may
22 experience enlarged prostates and increased serum prostate-specific antigen levels.

23 47. Secondary exposure to AndroGel can cause side effects in others. In 2009, the
24 FDA issued a black box warning for AndroGel prescriptions, advising patients of reported
25 virilization in children who were secondarily exposed to the gel. Testosterone may also cause

1 physical changes in women exposed to the drug and cause fetal damage with pregnant women
2 who come into secondary contact with AndroGel.

3 48. Defendants' marketing strategy beginning in 2000 has been to aggressively market
4 and sell their products by misleading potential users about the prevalence and symptoms of low
5 testosterone and by failing to protect users from serious dangers that Defendants knew or should
6 have known to result from use of its products.

7 49. Defendants successfully marketed AndroGel by undertaking a "disease awareness"
8 marketing campaign. This campaign sought to create a consumer perception that low
9 testosterone is prevalent among U.S. men and that symptoms previously associated with other
10 physical and mental conditions, such as aging, stress, depression, and lethargy were actually
11 attributable to "Low-T."

12 50. Defendants' advertising program sought to create the image and belief by
13 consumers and their physicians that the use of AndroGel was a safe method of alleviating their
14 symptoms, had few side effects and would not interfere with their daily lives, even though
15 Defendants knew or should have known these to be false, and even though the Defendants had
16 no reasonable grounds to believe them to be true.

17 51. Defendants purposefully downplayed, understated and outright ignored the health
18 hazards and risks associated with using AndroGel. Defendants deceived potential AndroGel
19 users by relaying positive information through the press, including testimonials from retired
20 professional athletes, and manipulating hypogonadism statistics to suggest widespread disease
21 prevalence, while downplaying known adverse and serious health effects.

22 52. Defendants concealed material relevant information from potential AndroGel
23 users and minimized user and prescriber concern regarding the safety of AndroGel.

24 53. In particular, in the warnings Defendants give in their commercials, online and
25 print advertisements, Defendants fail to mention any potential cardiac or stroke side effects and
falsely represents that they adequately tested AndroGel for all likely side effects.

54. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for AndroGel. If Plaintiff in this action had known the risks and dangers associated with AndroGel, the he would not have taken AndroGel and consequently would not have been subject to its serious side effects.

SPECIFIC FACTUAL ALLEGATIONS

55. Plaintiff Jesse Mitchell was prescribed and used AndroGel from approximately 2008 to 2012.

56. Plaintiff Jesse Mitchell viewed Defendants' advertising for AndroGel and decided to use the product after viewing those advertisements.

57. Plaintiff Jesse Mitchell's consumption of AndroGel caused physical and emotional impairment beginning on or about November 18, 2012, which affected his personal and professional life.

58. As a result of his use of AndroGel, Plaintiff Jesse Mitchell suffered physical and emotional injuries including, but not limited to, heart attack, which necessitated substantial treatment.

FIRST CAUSE OF ACTION **STRICT LIABILITY – FAILURE TO WARN**

59. Plaintiffs incorporate by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

60. AndroGel was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, Jesse Mitchell, of the dangerous risks and reactions associated with the subject product, including, but not limited to, its propensity to cause permanent physical injuries including, but not limited to, developing cardiovascular disease, strokes, myocardial infarcts, and other serious injuries, side effects, and even death; notwithstanding Defendants' knowledge of an increased

1 risk of these injuries and side effects over other forms of treatment for low testosterone. Thus,
2 AndroGel was unreasonably dangerous because an adequate warning was not provided.

3 61. AndroGel was manufactured and supplied by Defendants and was defective due to
4 inadequate post-marketing warnings or instructions because, after Defendants knew or should
5 have known of the risk of serious bodily harm from the use of AndroGel, Defendants failed to
6 provide an adequate warning to consumers and/or their health care providers of the defects of
7 the product, and/or alternatively failed to conform to federal and/or state requirements for
8 labeling, warnings and instructions, or recall, while knowing that the product could cause
9 serious injury and/or death.

10 62. Plaintiff Jesse Mitchell was prescribed and used AndroGel for its intended
11 purpose.

12 63. Plaintiff Jesse Mitchell could not have discovered any defect in the subject product
13 through the exercise of reasonable care.

14 64. Defendants, as manufacturers and/or distributors of the AndroGel, are held to the
15 level of knowledge of an expert in the field.

16 65. The warnings that were given by Defendants were not accurate, clear, and/or were
17 ambiguous.

18 66. The warnings that were given by Defendants failed to properly warn physicians of
19 the increased risks of permanent physical injuries including, but not limited to, heart attack,
20 stroke, thromboembolic events and death.

21 67. Plaintiff, Jesse Mitchell, individually and through his prescribing physician,
22 reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

23 68. Defendants had a continuing duty to warn Plaintiff Jesse Mitchell of the dangers
24 associated with AndroGel. Had Plaintiff Jesse Mitchell received adequate warnings regarding
25 the risks of AndroGel, he would not have used it.

69. As a direct and proximate result of Plaintiff Jesse Mitchell's reasonably anticipated use of AndroGel as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

SECOND CAUSE OF ACTION
STRICT LIABILITY – DESIGN DEFECT

70. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

71. AndroGel is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or that the foreseeable risks exceed the benefits associated with its design and formulation.

72. At all times material to this action, AndroGel was expected to reach, and did reach, consumers in the State of Oregon and throughout the United States, including Plaintiff Jesse Mitchell, without substantial change in the condition in which it was sold.

73. At all times material to this action, AndroGel was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

- a. When placed in the stream of commerce, AndroGel contained unreasonably dangerous design defects and was not reasonably safe for its intended use, subjecting Jesse Mitchell to risks that exceeded the benefits of the subject product including, but not limited to, permanent personal injuries including, but not limited to, developing cardiovascular disease, strokes, myocardial infarctions, and other serious injuries and side effects;

b. When placed in the stream of commerce, AndroGel was defective in design and formulation, making the use of AndroGel more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat low testosterone;

c. The design defects found in AndroGel existed before it left the control of the Defendants;

d. AndroGel was insufficiently and inadequately tested;

e. AndroGel caused harmful side effects in Plaintiff Jesse Mitchell and the public as a whole that outweighed any potential utility; and

f. AndroGel was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff Jesse Mitchell, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiffs.

74. In addition, at the time AndroGel left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff Jesse Mitchell's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff Jesse Mitchell's injuries without substantially impairing the products' utility.

THIRD CAUSE OF ACTION **NEGLIGENCE**

75. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though set forth herein.

76. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute,

1 market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the
2 risks and dangers of AndroGel.

3 77. At all times herein mentioned, Defendants negligently and carelessly
4 manufactured, designed, formulated, distributed, compounded, produced, processed, assembled,
5 inspected, distributed, marketed, labeled, packaged, prepared for use and sold AndroGel and
6 failed to adequately test and warn of the risks and dangers of AndroGel.

7 78. Despite the fact that Defendants knew or should have known that AndroGel
8 caused unreasonable, dangerous side effects, Defendants continued to market AndroGel to
9 consumers including Plaintiff, Jesse Mitchell, when there were safer alternative methods of
10 treating loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other
11 conditions AndroGel's advertising claims are caused by low testosterone.

12 79. Defendants knew or should have known that consumers such as Plaintiff Jesse
13 Mitchell would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary
14 care as described above.

15 80. Defendants' negligence was a proximate cause of Plaintiff Jesse Mitchell's
16 injuries, harm and economic loss, which Plaintiffs suffered, and will continue to suffer, as
17 described and prayed for herein.

18 **FOURTH CAUSE OF ACTION**
19 **BREACH OF IMPLIED WARRANTY**

20 81. Plaintiffs incorporate by reference here each of the allegations heretofore set forth
21 in this Complaint as though fully set forth herein.

22 82. Prior to the time that the aforementioned product was used by Plaintiff, Jesse
23 Mitchell, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that
24 AndroGel was of merchantable quality and safe and fit for the use for which it was intended.
25

1 83. Plaintiffs were and are unskilled in the research, design and manufacture of the
2 products and reasonably relied entirely on the skill, judgment and implied warranty of the
3 Defendants in using AndroGel.

4 84. AndroGel was neither safe for its intended use nor of merchantable quality, as
5 warranted by Defendants, in that AndroGel has dangerous propensities when used as intended
6 and will cause severe injuries to users.

7 85. As a result of the abovementioned breach of implied warranties by Defendants,
8 Plaintiff Jesse Mitchell suffered injuries and damages as alleged herein.

9 **FIFTH CAUSE OF ACTION**
10 **BREACH OF EXPRESS WARRANTY**

11 86. Plaintiffs incorporate by reference here each of the allegations set forth in this
12 Complaint as though fully set forth here.

13 87. At all times mentioned, Defendants expressly represented and warranted to
14 Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants to
15 their authorized agents or sales representatives, orally and in publications, package inserts and
16 other written materials intended for physicians, medical patients and the general public, that
17 AndroGel is safe, effective, fit and proper for its intended use. Plaintiff purchased AndroGel
18 relying upon these warranties.

19 88. In utilizing AndroGel, Plaintiff relied on the skill, judgment, representations, and
20 foregoing express warranties of Defendants. These warranties and representations were false in
21 that AndroGel is unsafe and unfit for its intended uses.

22 89. As a result of the abovementioned breach of express warranties by Defendants,
23 Plaintiff Jesse Mitchell suffered injuries and damages as alleged herein.
24
25

SIXTH CAUSE OF ACTION
FRAUD

90. Plaintiffs incorporate by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

91. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed AndroGel, and up to the present, willfully deceived Plaintiff by concealing from him, Plaintiff's physicians and the general public, the true facts concerning AndroGel, which the Defendants had a duty to disclose.

92. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using AndroGel. Defendants knew of the foregoing, that AndroGel is not safe, fit and effective for human consumption, that using AndroGel is hazardous to health, and that AndroGel has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff Jesse Mitchell suffered.

93. Defendants concealed and suppressed the true facts concerning AndroGel with the intent to defraud Plaintiffs, in that Defendants knew that Plaintiff Jesse Mitchell's physicians would not prescribe AndroGel, and Plaintiff Jesse Mitchell would not have used AndroGel, if they were aware of the true facts concerning its dangers and its lack of efficacy.

94. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff Jesse Mitchell suffered injuries and damages as alleged herein.

SEVENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

95. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though fully set forth herein.

1 96. From the time AndroGel was first tested, studied, researched, evaluated, endorsed,
2 manufactured, marketed and distributed, and up to the present, Defendants made
3 misrepresentations to Plaintiff Jesse Mitchell, his physicians and the general public, including,
4 but not limited to, the misrepresentation that AndroGel was safe, fit and effective for human
5 consumption. At all times mentioned, Defendants conducted a sales and marketing campaign to
6 promote the sale of AndroGel and willfully deceived Plaintiff Jesse Mitchell, his physicians and
7 the general public as to the health risks and consequences of the use of the abovementioned
8 product.

9 97. The Defendants made the foregoing representations without any reasonable
10 ground for believing them to be true. These representations were made directly by Defendants,
11 by sales representatives and other authorized agents of Defendants, and in publications and other
12 written materials directed to physicians, medical patients and the public, with the intention of
13 inducing reliance and the prescription, purchase and use of the subject product.

14 98. The representations by the Defendants were in fact false, in that AndroGel is not
15 safe, fit and effective for human consumption. Instead, using AndroGel is hazardous to health,
16 and AndroGel has a serious propensity to cause serious injuries to users, including but not
17 limited to the injuries suffered by Plaintiff Jesse Mitchell.

18 99. The foregoing representations by Defendants, and each of them, were made with
19 the intention of inducing reliance and the prescription, purchase and use of AndroGel.

20 100. In reliance on the misrepresentations made by the Defendants, and each of them,
21 Plaintiff Jesse Mitchell was induced to purchase and use AndroGel. If Plaintiff Jesse Mitchell
22 had known of the true facts and the facts concealed by the Defendants, he would not have used
23 AndroGel. His reliance upon Defendants' misrepresentations was justified because such
24 misrepresentations were made and conducted by individuals and entities that were in a position
25 to know the true facts.

101. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff Jesse Mitchell suffered injuries and damages as alleged herein.

EIGHTH CAUSE OF ACTION
NEGLIGENCE PER SE—VIOLATION OF 21 U.S.C. §§ 331(a) & 352

102. As part of their duty to exercise reasonable care, Defendants were obligated to follow public laws and regulations enacted to protect the safety of persons such as Plaintiff, Jesse Mitchell, including 21 U.S.C. § 331(a), § 352, and other statutes and regulations, which make it unlawful to sell misbranded prescription drug products.

103. The labeling for AndroGel failed to conform to the requirements of 21 U.S.C. § 352, including subsections (a), (c), and (j), and the requirements of 21 C.F.R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a), which prohibits the sale of misbranded drugs.

104. The label and package insert for AndroGel is misbranded within the meaning of 21 U.S.C. § 352(a) and (f) because it was false and misleading and failed to give adequate warnings and directions for use by physicians who prescribe AndroGel.

105. AndroGel is misbranded pursuant to 21 U.S.C. § 352 because:

(a) Words, statements, or other information required under that section are not prominently placed with such conspicuousness and in such ways as to render it likely to be read and understood by the ordinary individual or prescriber under customary conditions of purchase and use.

(b) The labeling does not bear adequate directions for use, and the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage, methods, or application in such manner and form as are necessary for the protection of patients.

(c) It is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

1 106. Because Defendants had a statutory duty under 21 U.S.C. § 352 (a) and (f) not to
2 misbrand AndroGel, and because they violated this duty, they are guilty of negligence per se.

3 107. AndroGel is misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was
4 not updated as new information became available that caused the labeling to become inaccurate,
5 false, or misleading.

6 108. Defendants violated 21 C.F.R. § 201.57 because:

7 (a) As shown, the labeling was not revised to include a warning as soon as
8 there was reasonable evidence of an association of a serious hazard with the drug
(i.e., heart attacks, strokes, and other blood clotting injuries).

9 (b) They failed to identify specific tests needed for selection or monitoring of
10 patients who took the prescription drug AndroGel. The safety considerations
11 regarding AndroGel are such that the drug should be reserved for certain
12 situations, and the Defendants failed to state such information.

13 (d) The labeling fails to describe serious adverse reactions and potential safety
14 hazards, and steps that should be taken if they occur.

15 (e) The labeling does not state an upper limit dosing beyond which safety and
16 effectiveness have not been established.

17 109. AndroGel violates 21 C.F.R. § 210.122 because the labeling and packaging
18 materials do not meet the appropriate specifications.

19 110. AndroGel violates 21 C.F.R. § 310.303 in that it is not safe and effective for its
20 intended use.

21 111. Defendants violated 21 C.F.R. § 310.305 and § 314.80 by:

22 (a) Failing to report adverse events associated with AndroGel as soon as
23 possible or at least within 15 days of the initial receipt by Defendants of the
24 adverse drug experience.

(b) Failing to conduct an investigation of each adverse event associated with AndroGel, evaluate the cause of the adverse event, submit follow-up reports within the prescribed 15 calendar days of receipt of new information or was requested by the FDA, and keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

(c) Failing to provide periodic reports to the FDA containing (1) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (2) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, (3) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated) and/or (4) a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

112. Defendants violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of AndroGel or otherwise received by Defendants from any sources, including information from any clinical or epidemiological studies, animal studies, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities.

113. Defendants failed to meet the standard of care set out in these statutes and regulations, which were intended for the benefit of individual consumers such as Plaintiff, Jesse Mitchell, making Defendants liable to Plaintiff. Because each of them violated the duties imposed by these statutes and regulations, they are guilty of negligence per se.

114. As a direct and proximate result of the actions and inactions of Defendants, Plaintiffs suffered damages, including personal injuries, economic damages, and non-economic

1 damages. Defendants' conduct was further wanton, egregious, and reckless so as to warrant the
2 award of punitive damages.

3 **NINTH CAUSE OF ACTION**
4 **LOSS OF CONSORTIUM**

5 115. Plaintiffs incorporate by reference here each of the allegations set forth in this
6 Complaint as though fully set forth herein.

7 116. Plaintiff, Kimberly Mitchell, at all times relevant was the lawful wife of Jesse
8 Mitchell.

9 117. As a direct, legal, and proximate result of the culpability and fault of Defendants,
10 be such fault through strict liability, negligence or otherwise, Plaintiff Kimberly Mitchell
11 suffered the loss of support, services, love, companionship, affection, society, intimate relations,
12 and other elements of consortium, all to her general damage in an amount in excess of the
13 jurisdictional minimum of this court.

14 118. Plaintiffs demand judgment against Defendants for compensatory and punitive
15 damages such as a jury may award, and such other relief as the Court deems just and proper in
16 order to remedy Plaintiff Kimberly Mitchell's loss of consortium.

17 **TENTH CAUSE OF ACTION**
18 **PUNITIVE DAMAGES ALLEGATIONS**

19 119. Plaintiffs incorporate by reference here each of the allegations set forth in this
20 Complaint as though fully set forth herein.

21 120. The acts, conduct, and omissions of Defendants, as alleged throughout this
22 Complaint were willful and malicious. Defendants committed these acts with a conscious
23 disregard for the rights of Plaintiff Jesse Mitchell and other AndroGel users and for the primary
24 purpose of increasing Defendants' profits from the sale and distribution of AndroGel.
25 Defendants' outrageous and unconscionable conduct warrants an award of exemplary and

1 punitive damages against Defendants in an amount appropriate to punish and make an example
2 of Defendants.

3 121. Prior to the manufacturing, sale, and distribution of AndroGel, Defendants knew
4 that said medication was in a defective condition as previously described herein and knew that
5 those who were prescribed the medication would experience and did experience severe physical,
6 mental, and emotional injuries. Further, Defendants, through their officers, directors, managers,
7 and agents, knew that the medication presented a substantial and unreasonable risk of harm to
8 the public, including Plaintiff Jesse Mitchell and as such, Defendants unreasonably subjected
9 consumers of said drugs to risk of injury or death from using AndroGel.

10 122. Despite its knowledge, Defendants, acting through its officers, directors and
11 managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately
12 failed to remedy the known defects in AndroGel and failed to warn the public, including
13 Plaintiffs, of the extreme risk of injury occasioned by said defects inherent in AndroGel.
14 Defendants and their agents, officers, and directors intentionally proceeded with the
15 manufacturing, sale, and distribution and marketing of AndroGel knowing these actions would
16 expose persons to serious danger in order to advance Defendants' pecuniary interest and
17 monetary profits.

18 123. Defendants' conduct was despicable and so contemptible that it would be looked
19 down upon and despised by ordinary decent people, and was carried on by Defendants with
20 willful and conscious disregard for the safety of Plaintiff, Jesse Mitchell, entitling Plaintiff to
21 exemplary damages.

22 **PRAYER FOR RELIEF**

23 **WHEREFORE**, Plaintiffs pray for judgment against the Defendants as follows, as
24 appropriate to each cause of action alleged and as appropriate to the particular standing of
25 Plaintiffs:

A. General damages in an amount that will conform to proof at time of trial;

- 1 B. Special damages in an amount within the jurisdiction of this Court and according to
2 proof at the time of trial;
- 3 C. Medical expenses, past and future, according to proof at the time of trial;
- 4 D. For past and future mental and emotional distress, according to proof;
- 5 E. Damages for loss of care, comfort, society, and companionship in an amount within
6 the jurisdiction of this Court and according to proof;
- 7 F. For punitive or exemplary damages according to proof;
- 8 G. Restitution, disgorgement of profits, and other equitable relief;
- 9 H. Injunctive relief;
- 10 I. Attorney's fees;
- 11 J. For costs of suit incurred herein;
- 12 K. For pre-judgment interest as provided by law;
- 13 L. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

14 Plaintiff demands a trial by jury on all counts and as to all issues.

15 Respectfully submitted this 17th day of November, 2014.

16 GOLDBERG & OSBORNE

17 /s/ David J. Diamond

18 David J. Diamond

19 D. Greg Sakall

Attorneys for Plaintiffs

20 I hereby certify that on the 17th day of November, 2014, I electronically transmitted the attached
21 document to the Clerk's Office using the CM/ECF System for filing.

22 /s/ K. Hampton